

PATENT APPLICATION  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Donald R. OWEN et al.

Application No.: Rule 53(b) Continuation-in-Part  
of Appln No. 10/617,130

Filed: February 2, 2004

Docket No.: 040219.04

For: APPARATUS AND METHOD FOR DETERMINING EFFECTS OF A SUBSTANCE ON  
AN ORGAN

INFORMATION DISCLOSURE STATEMENT


Director of the U.S. Patent and Trademark Office  
Washington, D.C. 20231

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date or the date of filing a CPA, OR (b) before the mailing date of a first Office Action on the merits in the present application. No certification or fee is required.
- ☒ 2. The references were cited by or submitted to the Office in Application No. 09/617,130, filed July 11, 2003, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).

Respectfully submitted,

  
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Date: February 2, 2004

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<p style="text-align: center;">DEPOSIT ACCOUNT USE AUTHORIZATION Please grant any extension necessary for entry; Charge any fee due to our Deposit Account No. 15-0461</p>
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Form PTO-1449 (REV. 8-83)		US Dept. of Commerce PATENT & TRADEMARK OFFICE		ATTY DOCKET NO. 040219.04		APPLICATION NO. Rule 53(b) Continuation in Part of Appln No. 10/617,130	
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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		5,699,793	12/23/97	Brasile			
		5,843,024	12/1/98	Brasile			
		5,702,881	12/30/97	Brasile et al.			
		5,643,712	7/1/97	Brasile			
		3,545,221	12/08/70	Swenson et al.			
		1,682,344	08/28/28	Lesieur			
		1,916,658	07/04/33	Davidson			
		3,406,531	10/22/68	Swenson et al.			
		3,607,646	10/21/71	de Roissart			
		3,632,473	01/04/72	Belzer			
		3,639,084	02/01/72	Goldhaber			
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		0 256 653	02/24/88	EUROPE			
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		"GLUTATHIONE S-TRANSFERASE PREDICTS OUTCOME OF MACHINE PRESERVED NHBD KIDNEYS", J.H. Loemen and C. Kootstra, Abstract submitted for presentation at XVIth International Congress of the Transplantation Society, Aug. 1996.					
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		"ORGAN PRESERVATION", J.H. Southard, Ph.D. and F.O. Belzer, M.D., <u>Principles of Organ Transplantation</u> , Chapter 10, pgs. 194-215, 1989.					
		"ORGANKO SERVIERUNGSMACHINE OKM 82", Von Dietmer Scholz et al., East German Article, 1983.					
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		"NUTRITIONAL ASPECTS OF AMBULATORY CARE-OXYGEN RADICALS AND DISEASE-NO. 1", Hoffmann-La Roche, Vol. 42, No. 3, pgs. 557-558, Sept. 1990.					
		"CEREBRAL ISCHEMIC INJURY", Blaine C. White, <u>Emergency Medicine-A Comprehensive Study Guide</u> , Second Edition, pgs. 9-10, 1988.					
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		3,660,241	05/02/72	Michielsen			
		3,738,914	06/12/73	Thorne et al.			
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		5,681,740	10/1997	Messier et al.			
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		0 297 723	01/04/89	EUROPE			
		1-213276	08/28/89	JAPAN			
		38 08 942	09/28/89	GERMANY			
		376 763	07/04/90	EUROPE			
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		3,892,628	07/01/75	Thorne et al.			
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		4,186,565	2/5/80	Toledo-Pereyra			
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		163 242 8	07/03/91	SOVIET UNION			
		93/00808	01/21/93	PCT			
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		3,962,439	06/08/76	Yokoyama et al.			
		3,995,444	12/07/76	Clark et al.			
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		96/32074	10/17/96	PCT			
		96/32157	10/17/96	PCT			
		2 226 482	01/04/73	GERMANY			
		760972	09/07/80	SOVIET UNION			
		0 096 997	12/28/83	EUROPE			
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
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		"90'S COULD SEE BRAIN INJURY REVERSAL", Rebecca Voelker, <u>American Medical News</u> , Nov. 17, 1989.					
		"COOLING BRAIN MAY LIMIT STROKE DAMAGE", <u>American Medical News</u> , p. 66, Nov. 17, 1989.					
		"DRUG MAY PRESERVE HEART TISSUE AFTER ATTACK", <u>The New York Times Company</u> , p. 3, Sept. 5, 1989.					
		"RADICAL THERAPY", <u>Scientific American</u> , Sept. 1987.					
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		4,242,883	01/06/81	Toledo-Pereyra			
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		4,378,797	04/05/83	Osterholm			
		4,393,863	07/19/83	Osterholm			
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		4,471,629	09/18/84	Toledo-Pereyra			
		4,474,016	10/02/84	Winchell			
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		4,494,385	12/22/85	Kuraoka et al.			
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		4,657,532	04/14/87	Osterholm			
		4,666,425	05/19/87	Fleming			
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		4,879,283	11/07/89	Belzer et al.			
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	
		5,157,930	10/27/92	McGhee et al.			
		5,200,176	04/06/93	Wong et al.			
		5,216,032	06/01/93	Manning			
		5,217,860	06/08/93	Fahy et al.			
		5,234,405	08/10/93	Klatz et al.			
		5,285,657	02/15/94	Bacchi et al.			
		5,328,821	07/12/94	Fisher et al.			
		5,338,662	08/16/94	Sadri			
		5,356,771	10/18/94	O'Dell			
		5,362,622	11/08/94	O'Dell et al.			
		5,383,854	01/24/95	Safar et al.			
		5,385,821	01/31/95	O'Dell et al.			
		5,395,314	03/07/95	Klatz et al.			
		5,434,045	07/18/95	Jost			
		5,437,633	08/01/95	Manning			
		5,472,876	12/05/95	Fahy			
		5,584,804	12/17/96	Klatz et al.			
		5,586,438	12/24/96	Fahy			
		5,599,659	02/04/97	Brasile et al.			
		5,712,084	01/27/98	Osgood			
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		WO 97/28449	08/07/97	PCT			
		WO 96/12191	04/25/96	PCT			
		WO 96/31779	10/10/96	PCT			
		WO 97/22003	06/19/97	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)							
		"EFFECT OF PHARMACOLOGIC AGENTS ON THE FUNCTION OF THE HYPOTHERMICALLY PRESERVED DOG KIDNEY DURING NORMOTHERMIC REPERFUSION", Rutger J. Ploeg et al., <u>Surgery</u> , Vol. 103, No. 6, pgs. 676-682, June 1988.					
		"INTERMEDIATE NORMOTHERMIC PERFUSION DURING COLD STORAGE OF ISCHEMICALLY INJURED KIDNEYS", J.G. Maessen et al., <u>Transplantation Proceedings</u> , Vol. 21, No. 1, pgs. 1252-1253, Feb. 1989.					
		"THE BENEFICIAL EFFECT OF INTERMEDIATE NORMOTHERMIC PERFUSION DURING COLD STORAGE OF ISCHEMICALLY INJURED KIDNEYS", Jos G. Maessen et al., <u>Transplantation</u> , Vol. 47, No. 3, pgs. 409-414, March 1989.					
		"THE ASYSTOLIC, OR NON-HEARTBEATING, DONOR", Gauke Kootstra, <u>Transplantation</u> , Vol. 63, No. 7, pgs. 917- 921, 1997.					
		"THE USE OF HEMOGLOBIN SOLUTIONS IN KIDNEY PERFUSIONS", F.H. Daniels et al., <u>CRC Critical Reviews In Biomedical Engineering</u> , Vol. 9, Issue 4, pgs. 315-345, 1984.					
		"NORMOTHERMIC RENAL ARTERY PERFUSION: A COMPARISON OF PERFUSATES", John D. Hughes et al., <u>Annals of Vascular Surgery</u> , Vol. 10, pgs. 123-130, 1996.					
		"IS NORMOTHERMIC PRESERVATION AN ALTERNATIVE TO HYPOTHERMIC PRESERVATION?", R. N. Dunn et al., <u>Organ Preservation Basic and Applied Aspects</u> , Chapter 38, pgs. 273-277, 1982.					
		"MILD HYPOTHERMIA GIVES BETTER FUNCTIONAL PRESERVATION THAN COLD OR NORMOTHERMIC PERFUSION OF RAT KIDNEYS", B.L. Kasiske et al., <u>Transplantation Proceedings</u> , Vol. 22, No. 2, pgs. 472-473, April 1990.					
		"STUDIES OF CONTROLLED REPERFUSION AFTER ISCHEMIA", Pierre L. Julia, MD et al., <u>The Journal of Thoracic and Cardiovascular Surgery</u> , Vol. 101, No. 2, pgs. 303-13, Feb. 1991.					
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		"URINARY $\pi$ -CLASS GLUTATHIONE TRANSFERASE AS AN INDICATOR OF TUBULAR DAMAGE IN THE HUMAN KIDNEY", Dr. Anders Sundberg et al., <u>Nephron</u> , Vol. 67, pgs. 308-316, 1994.					
		"EFFECT OF ISCHEMIA AND 24 HOUR REPERFUSION ON ATP SYNTHESIS IN THE RAT KIDNEY", C.E. Irazu et al., <u>Journal of Experimental Pathology</u> , Vol. 4, No. 1, pgs. 29-36, 1989.					
		"INTERMEDIATE NORMOTHERMIC HEMOPERFUSION OF RAT KIDNEYS: FUNCTIONAL ASPECTS AND A STUDY INTO THE EFFECT OF FREE RADICAL SCAVENGERS", A.O. Gaber, <u>Transplantation Proceedings</u> , Vol. XX, No. 5, pgs. 896-898, Oct. 1998.					
		"IMPROVEMENT OF POSTISCHEMIC KIDNEY FUNCTION BY REPERFUSION WITH A SPECIFICALLY DEVELOPED SOLUTION (BT01)", Pierre Julia, MD et al., <u>Annals of Vascular Surgery</u> , Vol. 9, pgs. s-81-s-88, 1995.					
		"ISCHEMIA WITH INTERMITTENT REPERFUSION REDUCES FUNCTIONAL AND MORPHOLOGIC DAMAGE FOLLOWING RENAL ISCHEMIA IN THE RAT", Richard S. Frank, MD et al., <u>Annals of Vascular Surgery</u> , Vol. 7, No. 2, pgs. 150-155, 1993.					
		"GRAFT CONDITIONING OF LIVER IN NON-HEART-BEATING DONORS BY AN ARTIFICIAL HEART AND LUNG MACHINE IN SITU", T. Endoh et al., <u>Transplantation Proceedings</u> , Vol. 28, No. 1, pgs. 110-115, Feb. 1996.					
		"MACHINE PERFUSION OF ISOLATED KIDNEY AT 37°C USING PYRIDOXALATED HEMOGLOBIN-POLYOXYETHYLENE (PHP) SOLUTION, UW SOLUTION AND ITS COMBINATION", T. Horiuchi et al., <u>Biomaterials, Art. Cells &amp; Immob. Biotech</u> , Vol. 20, Nos. 2-4,, pgs. 549-555, 1992.					
		"ANALYSIS OF THE OPTIMAL PERFUSION PRESSURE AND FLOW RATE OF THE RENAL VASCULAR RESISTANCE AND OXYGEN CONSUMPTION IN THE HYPOTHERMIC PERFUSED KIDNEY", R. Grundmann, M.D. et al., <u>Surgery</u> , Vol. 77, No. 3, pp. 451-461, March 1975.					
		"AN EXPERIMENTAL MODEL FOR ASSESSMENT OF RENAL RECOVERY FROM WARM ISCHEMIA", Paula Jablonski et al., <u>Transplantation</u> , Vol. 35, No. 3, pp. 198-204, March 1983.					
		"PRESERVATION OF THE ISOLATED KIDNEY UNDER NORMOTHERMIC CONDITIONS BY PERFUSION WITH PERFLUOROTRIBUTYLAMINE EMULSION", N.N. Kontuganov et al., Article published by Plenum Publishing Corporation, pp. 371-374, 1983.					
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		3,881,990	05/06/75	BURTON et al.			
		3,712,583	1-1973	MARTINDALE et al.			
		5,051,352	9-1991	MARTINDALE et al.			
		3,845,974	11-1974	PELLOUX-GERVAIS			
		5,013,303	5-1991	TAMARI et al.			
		5,879,329	3-1999	GINSBURG			
		5,928,182	7-1999	KRAUS et al.			
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		WO 97/43899	11/27/97	WIPO			
		WO 97/45527	12/04/97	WIPO			
		WO 96/29865	10/03/96	WIPO			
		WO 94/06292	03/31/94	WIPO			
		WO 91/09520	07/11/91	WIPO			
		0 376 763 A2	07/04/90	Europe			
		WO 88/05261	07/28/88	WIPO			
		545,332	10-1922	France			
		WO 96/13288	5-1996	WIPO			
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		5,326,706	7/1994	Yland et al.			
		6,024,698	2/2000	Brasile			
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	
		WO 86/00812	2/1986	WIPO			
		WO 91/14364	10/1991	WIPO			
		WO 97/45527	12/1997	WIPO			
		WO 97/46091	12/1997	WIPO			
		WO 99/15011	4/1999	WIPO			
		2 592 306	12/1985	France			
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		B.G. Rijkmans et al., "Six-Day Canine Kidney Preservation, Hypothermic Perfusion Combined with Isolated Blood Perfusion," February 1984, pp. 130-134.					
		Jan Van Der Wijk et al., "Six-Day Kidney Preservation in a Canine Model, Influence of a One-to-Four-Hour Ex Vivo Perfusion Interval," May 1983, pp. 408-411.					
		M.R. Buhl et al., "The Postanoxic Regeneration of 5'-Adenine Nucleotides in Rabbit Kidney Tissue during In Vitro Perfusion," 1976, pp. 175-181.					
		Gauke Kootstra et al., "A New Device Towards Intermediate Term Kidney Preservation - An Experimental Study," 1980, pp. 86-89.					
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		6,100,082	08/2000	Hassanein			
		6,046,046	04/2000	Hassanein			
		5,965,433	10/1999	Gardetto et al.			
		5,823,986	10/1998	Peterson			
		5,730,720	03/1998	Sites et al.			
		5,716,378	02/1998	Minten			
		5,622,429	04/1997	Heinze			
		4,462,215	07/1984	Kuraoka et al.			
		4,494,385	01/1985	Kuraoka et al.			
		5,356,771	10/1994	O'Dell			
		5,362,622	11/1994	O'Dell et al.			
		5,385,821	01/1995	O'Dell et al.			
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		WO 91/03934	04/1991	WIPO			
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		5,586,438	12/1996	Fahy			
		5,723,282	03/1998	Fahy et al.			
		5,821,045	10/1998	Fahy et al.			
		5,856,081	01/1999	Fahy			
		4,951,482	08/1990	Gilbert			
		4,837,390	06/1989	Reneau			
		4,717,548	01/1988	Lee			
		4,473,637	09/1984	Guibert			
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		4,242,883	01/1981	Toledo-Pereyra			
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		3,995,444	12/1976	Clark et al.			
		3,935,065	01/1976	Doerig			
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		3,892,628	07/1975	Thorne et al.			
		3,881,990	05/1975	Burton et al.			
		3,877,843	04/1975	Fischel			
		3,843,455	10/1974	Bier			
		3,810,367	05/1974	Peterson			
		3,777,507	12/1973	Burton et al.			
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		3,639,084	02/1972	Goldhaber			
		3,654,085	04/1972	Norr et al.			
		3,632,473	01/1972	Belzer et al.			
		3,545,221	12/1970	Swenson et al.			
		3,406,531	10/1968	Swenson et al.			
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